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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,189	01/02/2004	Haitham Matloub	CU-3389	3366
26530	7590	04/11/2006	EXAMINER	
LADAS & PARRY LLP 224 SOUTH MICHIGAN AVENUE SUITE 1600 CHICAGO, IL 60604			GHALI, ISIS A D	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/751,189	MATLOUB ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/4/05; 9/2/05; 1/9/06</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The receipt is acknowledged of applicants' IDS filed 01/04/2005; IDS filed 09/02/2005; and IDS and election both filed 01/09/2006.

Claims 1-14 were previously presented.

Claims 15-19 have been added.

#### ***Response to Election/Restrictions***

1. Applicant's election of Group I, claims 1-9 in the reply filed on 01/09/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without traverse** (MPEP § 818.03(a)).
2. Claims 10-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without traverse** in the reply filed on 01/09/2006.

**Claims 1-9 and 15-19 are included in the prosecution.**

***Specification***

3. The abstract of the disclosure is objected to because on page 11, line 18 the word "butyl" is listed within group consisting of polymers, while "butyl" is chemical group and not a polymer. Correction is required. See MPEP § 608.01(b).

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 3, 15, and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2 and 3 as amended as well as the newly added claims 15 and 17 are reciting new matters that are not described in the specification as originally filed. Claims 2 recites the limitation "up to 30 days" and claim 15 recites the limitation "up to 14 days" and these recitations permits periods less than 14 days. Nowhere in the specification applicants disclosed period less than 14 days. On page 18, line 5, applicants disclosed "from about 14 to about 30 days". Therefore applicants have no support for the limitations "up to 14 days" or "up to 30 days" that have open-ended lower limit. With regard to claims 3 and 17, claim 3 recites

the limitation "up to 300 microns" and claim 17 recites the limitation "up to 200 microns" and these limitations permit values below 200 microns. Nowhere in the specification applicants disclosed values less than 200 microns. On page 11, line 10, applicants disclosed "about 200 to about 300 microns". Therefore applicants have no support for the limitations "up to 300 microns" or "up to 200 microns" that have open-ended lower limit.

6. Claims 1-9 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification lacks description of therapeutic agents with regard to doses and concentration in combination with different polymers. On page 15 applicants disclosed 1-10% of antioxidant when silicone is used as the enrobing material. However, the specification lacks description of doses and concentration of other therapeutic agents when other polymers used as enrobing material. The specification lacks description for doses and concentration of any therapeutic active agents in the porous foam polymer layer.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "may be" in the second line of each claims renders the claims uncertain and in improper "Markush format". Proper Markush format to be followed in the claim should have the expression "selected from the group consisting of". Therefore, deletion of the expression "may be" from claim 4 and 5 is requested.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-9 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,352,508 ('508) combined with US 6,326,410 ('410).

US '508 teaches wound dressing comprising net substrate encapsulated in hydrophilic tacky resin coating leaving the apertures in the net substrate unoccluded, i.e. the coating has holes (abstract; col.2, lines 57-61). Coating is polyurethane that may contain active agents such as silver sulphadiazine (col.2, lines 62-64; col.3, lines 29-33). The coated substrate is laminated between two release liners (col.5, lines 52-54).

US '508 does not teach the encapsulated layer to be porous foam layer. US '508 does not teach the period of release of the therapeutic active agent, and the pores size.

The pores size does not impart patentability to the claims, absent evidence to the contrary.

The period of delivery of the therapeutic agent can be manipulated by the skilled artisan according to the polymer, active agent and to the condition to be treated.

US '410 teaches polyurethane foam that is suitable for wound contacting because it has low adherence and can deliver active agents such as antimicrobial agents to the wound including silver sulphadiazine (abstract; col.3, lines 14-15, 66-67; col.4, lines 1-3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound dressing comprising porous net substrate encapsulated with polyurethane that does not occlude the pores of the net as disclosed by US '508, and replace the net substrate with foam containing antibacterial agents as

disclosed by US '410, motivated by the teachings of US '410 that foam has low adherence and can deliver active agents such as antimicrobial agents to the wound, with reasonable expectation of having wound dressing comprising porous foam polymer material comprising active agent encapsulated with porous hydrophilic polyurethane that deliver active agent to wound site successfully.

12. Claims 1-9 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 2946553 ('553) combined with US 6,326,410 ('410).

DE '553 teaches wound treatment device comprising gelatinous polymer completely covered with permeable membrane that has pores (page 3, first and third paragraphs, the figure on 8 of the provided translation). The membrane can be polyurethane foam or open pore plastic film (page 3, forth paragraph). The gelatinous polymer can be polyvinyl alcohol and active agents can be mixed with the gelatinous polymer (page 4, second paragraph; page 5, first paragraph).

The difference between DE '553 and the present claims is that the reference does not teach the gelatinous polymer to be foamy. DE '553 does not teach the covering layer containing therapeutic active agents.

DE '553 does not teach the period of release of the therapeutic active agent, and the pores size.

The pores size does not impart patentability to the claims, absent evidence to the contrary.



The period of delivery of the therapeutic agent can be manipulated by the skilled artisan according to the polymer, active agent and to the condition to be treated.

US '410 teaches polyurethane foam that is suitable for wound contacting because it has low adherence and can deliver active agents such as antimicrobial agents to the wound including silver sulphadiazine (abstract; col.3, lines 14-15, 66-67; col.4, lines 1-3).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide wound treatment device comprising gelatinous polymer covered with porous material such as polyurethane foam as disclosed by DE '553, and replace the gelatinous polymer with foam containing antibacterial agents as disclosed by US '410, motivated by the teachings of US '410 that foam has low adherence and can deliver active agents such as antimicrobial agents to the wound, with reasonable expectation of having wound treatment device comprising porous foam material comprising active agent and completely covered with polyurethane foam that deliver active agent to wound site successfully.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali  
Examiner  
Art Unit 1615

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**ISIS GHALI**  
**PATENT EXAMINER**